

## MEMORANDUM

**DATE:** March 30, 2001

**TO:** National Human Research Protection Advisory Committee (NHRPAC)

**FROM:** Felice J. Levine and Jeffrey M. Cohen, Co-Chairs

**RE:** Social and Behavioral Science Working Group Initial Report

We are pleased to provide an overview of the Social and Behavioral Science Working Group and to have the privilege of serving as Co-Chairs. As part of the process of establishing this Working Group, we drew upon recent reports, testimony, and the NHRPAC discussion of social and behavioral science issues in December 2000. Also, we consulted with Mary Faith Marshall and Kate-Louise Gottfried, who shared our view that it was important for this Working Group to provide NHRPAC with a report that contained concrete recommendations that could be effectively implemented in a timely fashion.

While some of our ambitions may be longer term, we essentially see our Working Group as defining a year-long set of objectives culminating in a report. We anticipate that, at each NHRPAC meeting (starting this summer), we should be positioned to provide interim reports on issues we are addressing and the best of our thinking on ways to improve the operations of the human subjects protection system as it relates to social and behavioral research. We see the process as an iterative one where we seek to interrogate the "fault" lines and troublespots in the system (including of investigators' understanding of it) and to offer specific solutions. In many respects, we do not per se see the regulations governing human subjects protection to be problematic (although there are important areas where clarifications, refinements, and much more inclusive language may be necessary). We do think, however, that in actual practice there are serious gaps in Institutional Review Boards and others understanding of the Common Rule as well as of human subjects considerations as they relate to social and behavioral science research.

**Working Group Goals.** Attached is a working outline to guide the Social and Behavioral Science Working Group (entitled Initial Report to NHRPAC). As we see it, the Social and Behavioral Science Working Group has two primary goals: to develop guidelines to help Institutional Review Boards (IRBs) more effectively administer the human subjects protection system, and to make specific

recommendations regarding additions or changes to the Common Rule with respect to the social and behavioral sciences. Our intent for this Working Group is to build upon the best available knowledge of how the system is operating, key issues and concerns as they relate to the social and behavioral sciences, and best ethical practices in these fields. We also seek (especially over this year) to be broad in our interests and input—including convening meetings of knowledgeable scientists at annual meetings of social and behavioral science societies; consulting with directors of major data archives on use of secondary data and issues of confidentiality, anonymity, and consent; and seeking information from those with considerable experience serving on IRBs that review social and behavioral science studies involving human participants.

**Composition of Working Group.** Including the Co-Chairs, the Social and Behavioral Science Working Group is comprised of 13 members (see attached). Members bring longstanding interest and expertise on human subject protection and considerable breadth of knowledge across domains of social and behavioral science inquiry, methods, and populations of study (including vulnerable populations). The Working Group includes persons from Federal agencies most centrally involved in the support of social and behavioral research. Also, it includes three members of NHRPAC (i.e., Drs. Jennie Joe and Jonathan Moreno in addition to Dr. Levine). In addition, two members—Drs. Hauser and Sieber—were asked to participate as active researchers in the social and behavioral sciences with substantive expertise on human subjects issues but without any formal connection to NHRPAC or to an agency serving as an ex officio member.

**Organizational Meeting.** The Social and Behavioral Science Working Group held its first meeting on March 20, 2001. Given the shortness of time to schedule the meeting, only half of the members were able to participate, but all were provided with background packets. Cohen, Levine, Kington, Pritchard, Rubin, and Sieber (by speaker phone) were present from the Working Group; Gottfried also attended. The purpose of the first meeting was to consider a framework to guide the activities of the working group and to work out the general parameters of a schedule. In many respects, this first meeting was an “organizational session.” The emphasis was on defining issues and activities and being open to a range of possible thrusts. The meeting lasted just under three hours.

**Agenda of Work and Schedule.** As noted above, the Initial Report to NHRPAC sets forth the key issues and anticipated activities to be undertaken by the Social and Behavioral Science Working Group over this first year (through the end of March 2001). We expect at that time to have ready a final report to NHRPAC. We also plan to provide NHRPAC with interim quarterly briefings timed to the meetings of NHRPAC that will address specific issues receiving special attention by the Working Group. We hope through the vehicle of these interim reports

both to brief NHRPAC in an ongoing way and also to benefit from the feedback, questions, and counsel of the full Advisory Committee.

The Working Group plans to meet for a full day in May, and currently Working Group members are being polled for their best dates. In preparation for that meeting, specific members of the Working Group are (1) reviewing key reports and testimonies to ensure that core issues have been fully identified and specified, (2) examining ethics codes from the social and behavioral science societies in terms of the nature of the guidance being provided on human subjects protection issues, and (3) completing work on a literature review that focuses on empirical studies of Institutional Review Boards and their work.

At the March meeting, the group discussed some of the key elements of the operating plan for the Social and Behavioral Science Working Group. (See the Initial Report to NHRPAC.) This operating plan will be further refined through e-mail communication (a restricted listserv will be established) and finalized at the May meeting of the Working Group. NHRPAC's suggestions and additional ideas are encouraged at the meeting on April 10.

# **SOCIAL AND BEHAVIORAL SCIENCE WORKING GROUP**

## **Initial Report to NHRPAC**

### **March 2001**

#### **Core Goals**

- To develop guidelines to help Institutional Review Boards (IRBs) review social and behavioral research involving human subjects
- To make specific recommendations regarding additions or changes to the Common Rule relevant to the social and behavioral sciences

#### **Key Issues for Working Group**

- *Issues of Scientific Substance*
  - Identification of risk in the social and behavioral science
    - Types of risk
    - Levels of risk
    - Relationship between risk, methods, substance of study, and subject populations
  - What is "research" and what is "human interaction"
    - Overall meaning and intent of concepts
    - In secondary analysis of data sources and public use files
    - In observations of public places
  - Consent and written consent (also timing and amount of disclosure)
  - Human subjects protection under various methodological conditions
    - Longitudinal studies
    - Non-invasive experimental studies
    - International research
  - Education of students—classroom research and student training
- *Issues Pertaining to the Human Subjects Protection System*
  - How it presents itself vis-à-vis the social and behavioral sciences
    - Coverage and examples in materials and products
    - Presence and expertise in staffing and leadership
  - IRBs and their readiness to review social and behavioral research
    - Knowledge of social and behavioral science research
    - Knowledge of rules and their flexible application
    - Composition of IRBs and other issues relating to expertise
- *Issues Pertaining to Social and Behavioral Science Researchers*
  - Knowledge and educational needs regarding ethical practices
  - General training in human subjects protection guidelines
  - Awareness of potential risks in social and behavioral research

Awareness of conflicts and financial conflicts  
Educational needs relating to the Common Rule and role of IRBs

## **Information that Would be Useful to Obtain**

What data do we need to have on IRBs; how/why would it be useful?  
# of social and behavioral science proposals reviewed each year  
# reviewed by IRBs specializing in social and behavioral science  
# IRBs specializing in the social and behavioral science  
# of IRBs  
Empirical studies of IRBs  
Ethical guidelines of scientific societies in social and behavioral sciences  
Key literature important to know

## **Operating Plan for the Social and Behavioral Science Workgroup**

Components of work for 2001-2002

### **Key tasks**

Outreach to social and behavioral science community  
The Working Group will arrange sessions at the meetings of various professional associations  
Input from other human subjects protection experts  
The Working Group will call upon outside experts for briefing and possibly to prepare "white papers" on issues of concern  
Data Gathering  
The Working Group will assess extant data and also obtain some systematic information on IRBs and the social and behavioral sciences  
Education  
The Working Group will collect and/or develop a series of case studies to train IRBs and investigators

### **Products**

Working memoranda on key issues (see outline above)  
Products from working group activity ("white papers," case studies)  
Report to NRPAC

# **Social and Behavioral Sciences Working Group**

## **National Human Research Protection Advisory Committee**

**Dr. Jeffrey M. Cohen (Co-Chair)**  
**Associate Director for Education**  
**Office for Human Research**  
**Protections (OHRP)**

**Dr. Robert M. Hauser**  
Vilas Research Professor of Sociology

Center for Demography of Health  
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